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Dkt. 48965-B/JPW/SHS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Virginia M. Litwin, et al.

U.S. Serial No.: 09/891,062 Examiner: J. Parkin

Filed : June 25, 2001 Art Unit: 1648

For : COMPOUNDS CAPABLE OF INHIBITING HIV-1

INFECTION

1185 Avenue of the Americ New York, New York 10036

January 7, 2002

Honorable Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on PTO-1449 form attached hereto as **Exhibit A.** A Copy of below listed reference 4 is attached hereto as **Exhibit 1**.

- 1. U.S. Patent No. 5,071,964, Dec. 10, 1991, Dustin et al.;
- 2. U.S. Patent No. 5,091,513, February 25, 1992, Huston et al.;
- U.S. Patent No. 5,854,400, issued December 29, 1998, Chang,
 T.W., et al.;
- 4. International Publication Number WO 97/26009, International Publication Date July 24, 1997, PCT International Application No. PCT/US97/00758, filed January 17, 1997 (Exhibit 1);

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PCH CENTER TOO SOO Abaza, M.-S.I. and M.Z. Atassi, (1992), "Effects of amino 5. acid substitutions outside an antigenic site on protein antibodies binding to monoclonal of predetermined specificity obtained by peptid immunization: demonstration with region 94-100 (antigenic site 3) of myoglobin" J. Prot. Chem. 11(5): 433-443;

- Alexander, H., et al., (1992), "Altering the antigenicity 6. of proteins" Proc. Natl. Acad. Sci. USA 89: 3352-3356;
- 7. Ashorn P.A., et al., (1990) "Human immunodeficiency virus envelope glycoprotein/CD4-mediated fusion of nonprimate cells with human cells" J. Virol. 64:2149-2156;
- 8. Attanasio et al., (1991) "Anti-Idiotypic Antibody Response To Monoclonal Anti-CD4 Preparations In Non-Human Primate Species" <u>J.Immun.</u> 146:507-514;
- 9. Broder C.C., et al., (1993) "The block to HIV-1 envelope glycoprotein-mediated membrane fusion in animal cells expressing human CD4 can be overcome by a human cell component(s) " Virology 193:483-491;
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- Clapham PR., al., (1991) "Specific cell surface 11. et requirements for the infection of CD4-positive cells by human immunodeficiency virus types 1 and 2 and by simian immunodeficiency virus" Virology 181:703-715;

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- 13. Dragic T., et al., (1992) "Complementation of murine cells for human immunodeficiency virus envelope/CD4-mediated fusion in human/murine heterokaryon" <u>J. Virol.</u> 66:4794-4802;
- 14. Dragic T., Picard L., and Alizon M., (1995) "Proteinase-resistant factors in human erythrocyte membranes mediate CD4-dependent fusion with cells expressing human immunodeficiency virus type 1 envelope glycoproteins" J. Virol. 69:1013-1018;
- 15. Golding H., Dimitrov DS., and Blumenthal R., (1992) "LFA-1 adhesion molecules are not involved in the early stages of HIV-1 env-mediated cell membrane fusion" <u>AIDS Res. Hum.</u>

 Retroviruses 8:1593-1598;
- 16. Harrington RD., and Geballe AP., (1993) "Cofactor requirement for human immunodeficiency virus type 1 entry into a CD4-expressing human cell line" <u>J. Virol</u> 67:5939-5947;
- 17. Hattori et al., (1989) "Involvement of Tryptase-Related Cellular Protease(s) In Human Immunodeficiency Virus Type I Infection" FEBS Letters 248:48-52;
- 18. Hildreth et al., (1989) "Involvement Of A Leukocyte Adhesion Receptor (LFA-1) In HIV-Induced Syncytium Formation" Science 244:1075-1078;

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- 20. Karwowska, S., et al., (1991), "Passive immunization for the treatment and prevention of HIV infection" Biotech.
 Therap. 2(1-2): 31-48;
- 21. Katinger, H., (1994), "Human monoclonal antibodies for passive immunotherapy of HIV-1" <u>Antibiot. Chemother.</u> 46: 23-37;
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- 23. Queen et al., (1989) "A Humanized Antibody That Binds to The Interleukin 2 Receptor" Proc Natl Acad. Sci. 86:10029-10033;
- 24. Sato et al., (1992) "Anti-CD7 Reagents inhibit HIV-1 Induced Syncytium Formation" <u>International Conference on AIDS</u> 81:PA5, POA2017;
- 25. Sato, A.I., et al., (1994) "Identification of CD7 glycoprotein as an accessory molecule in HIV-1-mediated syncytium formation and cell free infection" <u>J. Immunol.</u> 152: 5142-5152;
- 26. Sato, A.I., et al., (1995), "A simple and rapid method for preliminary evaluation of in vivo efficacy of anti-HIV compounds in mice" Antivir. Res. 27: 151-163;

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27. Schanberg et al., (1995), "Characterization of Human CD7 Transgenic Mice" <u>J. of Immun.</u> 146:507-514;

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- 29. Tulip, W.R., et al., (1992), "Crystal structures of two mutant neuraminidase-antibody complexes with amino acid substitutions in the interface" J. Mol. Biol. 227: 149-159;
- 30. Valentin et al., (1990) "The Leukocyte Adhesion Glycoprotein CD18 Participates In HIV Induced Syncyia Formation In Monocytoid And T-Cells" J. Immunology 144:934-937; and
- 31. Wang et al., (1994) "Deletion of T Lymphocytes In Human CD4
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 Antibodies From AIDS Patients" <u>Eur. J. Immunol.</u> 24:15531557.

The subject application is a continuation of U.S. Serial No. 08/118,415, filed on July 17, 1998. The above listed references 7, 9, 11-13, 14-16, 22, 25 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on October 1, 1999, in connection with U.S. Serial No. 09/118,415. The above listed references 1, 2, 8, 10, 17, 18, 23, 24, 27, 30, 31 were cited in a search report in connection with International Publication Number WO 97/26009, International Publication Date July 24, 1997, PCT International Application No. PCT/US97/00758, filed on January 17, 1997, a foreign counterpart of the subject application. A copy of the



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search report is attached hereto as **Exhibit B**. The above listed references 3, 5, 6, 19-21, 26, 28, 29 were previously cited by the United States Patent and Trademark Office in an Office Actioln issued on February 11, 2000, in connection with U.S. Serial No. 09/118,415. Accordingly, under 37 C.F.R. §1.98(d) copies of these references are not required to be provided to the United States Patent and Trademark Office, since they were previously cited by, or submitted to, the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120. A copy of the above-listed reference in attached hereto as Exhibit 1.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone either of them at the number provided below.

Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully Submitted

certify hereby that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

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